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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/557,955 04/25/00 PENFOLD

Y PM 266810

EXAMINER

HM12/0424

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FIELDS, I

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/557,955

Applicant(s)

PENFOLD ET AL.

Examiner

Ilesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/935,537.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendment filed April 25, 2000 (Paper No. 2) has been received and entered. Claim 1 has been cancelled according to Applicant's request. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/935537, filed on September 23, 1997.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2-10 are vague and indefinite in recitation of analyte "analogue". One skilled in the art would be unable to determine the meets and bounds of such a limitation. For instance, what constitutes as an analyte analogue? Without a clear definition as to what constitutes as an analyte analogue one of skill in the art would be unable to replicate the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by May et al.

The claims are drawn to an assay device wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be detected.

May et al. (US Patent 5,622,871) disclose an assay device wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be detected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 2-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. in view of Sawai et al.

The claims are drawn to an assay device and a reagent wherein the device comprises an immobilized anti-rabbit antibody and the reagent is a coloured latex particle sensitized to a murine monoclonal antibody and a rabbit antibody.

The teachings of May et al. are set forth above.

May et al. does not teach of an assay device or a reagent wherein a detection zone contains an immobilized anti-rabbit antibody and the reagent is a coloured latex particle sensitized to a murine monoclonal antibody and a rabbit antibody.

Sawai et al. (US Patent 4,224,304) teach of a method of preparing insoluble carrier particles such as coloured latex particles. Sawai et al. further teach of a method of preparing antibody sensitized latex particles. Sawai et al. further teach that the latex particles ideally have a diameter of 0.3 to 0.6 microns.

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Given that 1) May et al. has taught of an assay device wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be easily detected and that 2) Sawai et al. has taught of a method of preparing coloured latex particles sensitized to antibodies it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a reagent and/or an assay device comprising a particulate sensitized to a binding agent such as an antibody. One would have been motivated to make such a reagent or device because they have wide industry application and can be used as diagnostic tools.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

April 23, 2001



MARK NAVARRO
PRIMARY EXAMINER